

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2010 has been entered.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. James D. DeCamp on September 23, 2010.

The application has been amended as follows:

This application is in condition for allowance except for the presence of claims 39-44 directed to an election non-elected without traverse. Accordingly, **claims 39-44** been cancelled.

Claim 45 has been amended to read:

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45. A process for the continuous wet granulation of a powder material, comprising the steps of:

- (a) providing an apparatus comprising multiple intermeshing screws,
- (b) feeding a powder material to a first transport zone of the apparatus, the first transport zone comprising multiple, intermeshing, co-rotating screws, a section of each screw where the blades of one screw are parallel with the blades of the other screw,
- (b) (c) feeding a granulating liquid to said first transport zone
- (e) (d) continuously advancing said powder material and said granulating liquid from said first transport zone to an agglomeration zone downstream of said first transport zone for agglomerating said wet powder material,
- (d) (e) transporting said agglomerated material from said agglomeration zone to a second transport zone means downstream of said agglomeration zone for producing granules, said second transport zone having an aperture positioned collinearly to said transport zone, and
- (e) (f) directly discharging said granules from said second transport zone through said aperture.

Claim 55 has been amended to read:

55. The continuous wet granulation process according to claim 45, further comprising a granule drying step (f) (g) subsequent to discharging step (e) (f).

Claim 56 has been amended to read:

56. The continuous wet granulation process according to claim 45, further comprising a granule dry milling step subsequent to discharging step (e) (f).

Claim 61 has been amended to read:

61. The continuous wet granulation process according to claim 45, wherein the process further comprises a step wherein granules of (e) (f) are used to make tablets, effervescent granules, sachets, or filling hard capsules.

Claim 62 has been amended to read:

62. The continuous wet granulation process according to claim 55, wherein the process further comprises a step wherein the granules of (f) (g) are used to make tablets, effervescent granules, sachets, or filling hard capsules.

Claim 66 has been amended to read:

66. A process for the continuous wet granulation of a poorly soluble drug, comprising the steps of:

- (a) providing an apparatus comprising multiple intermeshing screws,
- (b) feeding a poorly soluble drug in powder form to a first transport zone of the apparatus, the first transport zone comprising multiple, intermeshing, co-rotating screws, a section of each screw where the blades of one screw are parallel with the blades of the other screw,
- (b) (c) feeding a granulating liquid to said first transport zone
- (e) (d) continuously advancing said poorly soluble drug and said granulating liquid from said first transport zone to an agglomeration zone downstream of said first transport zone for agglomerating said wet poorly soluble drug,
- (d) (e) transporting said agglomerated material from said agglomeration zone to a second transport zone means downstream of said agglomeration zone for producing granules, said second transport zone having an aperture positioned collinearly to said transport zone, and
- (e) (f) directly discharging said granules from said second transport zone through said aperture.

The following is an examiner's statement of reasons for allowance:

As explained in the rejection mail April 1, 2010, Sugano et al. (US 4,416,606), henceforth **Sugano**, teaches most of the limitations recited by independent **claim 45**.

Two allowable features distinguish the claimed invention from Sugano's.

The first allowable feature is the fact that Sugano's blades are not intermeshing or interdigitating. First, it appears from Sugano's figure 1 that the blades do not intermesh. Second, if the blades did intermesh, Sugano's screws could not rotate

because: (a) if they co-rotated, the antiparallel blades in zones I and II₂ would clash and (b) if they counter-rotated, the parallel blades in zone II₁ would clash. Therefore, making Sugano's blades intermesh would incapacitate Sugano's apparatus.

The second allowable feature is the parallel orientation of the blades or flights of the screws in the first transport zone. Applicant's first transport zone (figure 1:4) corresponds to Sugano's feeding zone (figure 1:I). As can be seen from the figures, in that region, the blades of Applicant's screws are parallel from screw to screw, while the blades in Sugano's adjacent screws lean in intersecting directions. The direction of Sugano's blades lean determines the direction in which they convey the charge. In Sugano's zone II₂, the blades (4) are backward conveying blades (3:8-9). Sugano's feeding zone I, which corresponds to Applicant's first transport zone, is a mirror image of Sugano's zone II₂. As one would expect from a feeding zone, zone I is a forward conveying zone, as its blades (3) are forward conveying blades (3:7). The feeding zone would not be effective as such if the blades were parallel from screw to screw because then there would be backward conveying blades mixed with forward conveying blades. Therefore it would not have been obvious to one of ordinary skill in the art to replace Sugano's antiparallel blade arrangement in zone I with an arrangement in which all the blades are parallel as claimed by Applicant.

New independent **claim 66** recites limitations similar to those of claim 45 and is allowed for the same reason.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magali P. Slawski whose telephone number is (571) 270-3960. The examiner can normally be reached on Monday through Thursday 9:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer K. Michener can be reached on (571) 272-1424. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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